JUN 2 0 2000

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510(K) Summary
for
3D-MSPECT

1. SPONSOR

The Regents of the University of Michigan
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Ann Arbor, MI 48109-0028

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Date Prepared: March 29, 2000

2. DEVICE NAME

Proprietary Name: 3D-MSPECT
Common/Usual Name: Application Software for Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

3. PREDICATE DEVICE

ADAC Laboratories 3D-MSPECT (K980867)

4. INTENDED USE

The 3D-MSPECT application software is intended to be used for processing, quantification, and multidimensional review of reconstructed cardiac emission tomographic studies.

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5. DEVICE DESCRIPTION

3D-MSPECT is a comprehensive cardiac SPECT application designed to review and quantitatively analyze cardiac ECT nuclear medicine patient studies. 3D-MSPECT operates as an independent application on several different platforms. The application provides tools for processing and displaying standard ungated and ECG gated cardiac SPECT images on both a slice-by-slice basis and as 3-dimensional surface-rendered images in many user selectable formats. Additionally, it provides quantitative assessments of heart function by computing and displaying left ventricular chamber volumes, ejection fraction, and transient ischemic dilitation (TID) values and provides an assessment of the data set(s) in comparison to a similar patient population with a low likelihood of cardiac disease. Physicians use this information to assess the anatomical and physiological functionality of the heart and to analyze for the presence of myocardial perfusion and function defects. 3D-MSPECT provides a single, user-friendly, intuitive environment within which the operator, technologist, or physician can efficiently process and review all cardiac SPECT perfusion studies.

3D-MSPECT provides customers with the ability to process, analyze, and display reconstructed cardiac tomographic studies of all types. The application allows users to select from among a number of different quantification and display routines through a standardized user interface. The application also allows users to select from a number of different single or multi-dimensional display(s). 3D-MSPECT can be used to display the left ventricular endocardial and epicardial surfaces, polar maps indicating perfusion, wall thickening, wall motion and perfusion reversibility between stress and resting conditions, 3D surface-rendered images of the left ventricle, and 2D images in short axis, horizontal long, and vertical long axis format. All of the image formats can be viewed as a single dataset or as a comparison of related data sets (i.e., stress and rest conditions, pre- and post-revascularization). Among the several optional display screens are side-by-side displays optimized for the review of uncorrected and attenuation corrected cardiac images.

A Normals Database Generator is an integrated feature of 3D-MSPECT that provides the individual user with a set of tools for generating site-, patient population- or protocol-specific normal data files. Site-specific Normals Databases are integrated seamlessly into the application for research or daily clinical use. This is a sophisticated, user-friendly module that provides individual subject and population

statistics and the ability to review and edit the included studies (n=20 to 256) at the user's convenience.

The intent of this software application is to provide the physician with an adjunctive tool to aid in the diagnostic interpretation of myocardial perfusion SPECT images. It is not meant to replace or eliminate the standard visual analysis of the myocardial perfusion SPECT images. The physician should integrate all of the patient's clinical and diagnostic information prior to making a final interpretation of the SPECT study.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence for the 3D-MSPECT application software is based on both intended use and technical specifications. The University of Michigan 3D-MSPECT has the same intended use as the ADAC 3D-MSPECT, that is, for processing and display of reconstructed cardiac tomographic studies. The University of Michigan 3D-MSPECT application has the same source code lineage as the ADAC 3D-MSPECT application. Functionally, both applications provide the same quantitative parameters and qualitative displays. The main difference between these programs is that the ADAC 3D-MSPECT application can only run on the ADAC Pegasys computers (Pegasys X, PegUltra), while the University of Michigan 3D-MSPECT application can run on the DEC Alpha, SUN Sparc, Pentium Linux, and Windows 95/98 and NT platforms.

The safety of this program has been established through various stages of software development that include initial design, coding, module verification, and validation. The safety and effectiveness has been established using computer simulation studies, phantom measurements and in-house clinical validations. The clinical validations include (1) functional validation of the left ventricular ejection fraction and wall motion data involving 89 patients with contrast ventriculography data and (2) perfusion validation involving 340 patients with angiographic correlates for the detection of coronary heart disease. The accuracies of the parameters reported by 3D-MSPECT are equivalent to or higher than those obtained with other FDA-cleared quantitative analysis programs. We contend that the methods employed in the development and validation of the University of Michigan 3D-MSPECT application have demonstrated its safety and effectiveness. The 3D-MSPECT application is substantially equivalent to the ADAC 3D-MSPECT application which was cleared for marketing in June 1998. The University of Michigan 3D-MSPECT application is intended for the same purpose and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K001026
3D-MSPECT
Dated: March 29, 2000
Received: March 30, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001026

Device Name: 3D-MSPECT

Indications For Use:

The University of Michigan 3D-MSPECT application is intended to provide processing, quantification, and multidimensional review of reconstructed cardiac emission tomographic studies.

(Please do not write below this line –Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001026

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)